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| 10/716,360 | 11/18/2003 | Robert J. Thomas | 1440.2032-001 | 6678 |
| 21005 7590 06/19/2009 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133 | | | | |
| EXAMINER | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/716,360

Applicant(s)

THOMAS ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Appeal Brief Filed on March 12th, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. In view of the appeal brief filed on March 12th, 2009, PROSECUTION IS HEREBY REOPENED. A new grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Patricia Bianco/.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1-3, 6-8 and 10** are rejected under 35 U.S.C. 102(b) as being anticipated by Faithfull et al. (US 6,041,777).
4. **As to claim 1**, Faithfull teaches an apparatus that comprises a PAP device for sleep therapy (see col. 21 lines 60-65), the PAP device further comprising a source of carbon dioxide (the expired gases is defined as a source of carbon dioxide; see col. 20 lines 60-65); an assembly for combining pressurized air from the PAP device with substantially low concentrations of the carbon dioxide resulting in a gas mix (the ventilation conduit 118 is defined as the assembly where low concentration of carbon dioxide and pressurized air mix (the low concentration of carbon dioxide enter reservoir 154 (see col. 21 lines 1-11) and exits from the reservoir to enter ventilation conduit 118 which already comprises ambient gas (see col. 20 lines 60-65))) ; and a patient centric space ventilator, space module (PCVSM) coupled to the assembly providing the resulting gas mix for inhalation by a given target, said inhalation of the gas mix effecting respiratory stability of said target (see col. 20 lines 40-50).
5. **As to claim 2**, Faithfull teaches an apparatus wherein the assembly includes a sensor for measuring air flow (see col. 22 lines 10-20).
6. **As to claim 3**, Faithfull teaches an apparatus wherein the PCVSM includes any of a facemask, and a nasal cannula (see col. 20 lines 40-50).
7. **As to claim 6**, Faithfull teaches an apparatus wherein the assembly and PCVSM is a computer processor 132 controlled to modulate concentration of carbon dioxide in the gas mix (see col. 22 lines 20-30).
8. **As to claim 7**, Faithfull teaches an apparatus wherein the computer processor modulates concentration of CO₂ in the gas mix as a function of any combination of sensed concentration of

carbon dioxide in the PCVSM, sensed target state and detected system changes (**see col. 22 lines 10-35**).

9. **As to claim 8**, Faithfull teaches methods steps of providing a substantially low concentration of carbon dioxide to a PAP device used for sleep therapy; combining pressurized air from the PAP device used for sleep therapy with the carbon dioxide to form a gas mix having stabilizing effects on breathing (**the ventilation conduit 118 is defined as the assembly where low concentration of carbon dioxide and pressurized air mix (the low concentration of carbon dioxide enter reservoir 154 (see col. 21 lines 1-11) and exits from the reservoir to enter ventilation conduit 118 which already comprises ambient gas (see col. 20 lines 60-65))**), the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems; and delivering the gas mix to a subject with the PAP device used for sleep therapy (**see col. 40 lines 60**).
10. **As to claim 10**, Faithfull teaches a method step of combining includes utilizing a face mask worn by a target patient (**see col. 20 lines 40-60**).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims **4, 5, 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al. (US 6,041,777).

14. **As to claims 4 and 5**, Faithfull substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose concentration of carbon dioxide in the gas mixture that is between about 0.5% and about 2%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Faithfull's invention by providing a concentration of carbon dioxide in the gas mixture that is between about 0.5% and about 2% to stabilizing effect on respiration during sleep, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

15. **As to claims 11 and 12**, Faithfull substantially discloses claimed invention; see rejection of claim 8 above, but does not disclose a method step of employing carbon dioxide at concentration in the range of about 0.5% and about 2%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Faithfull's invention by employing carbon dioxide at concentration in the range of about 0.5% and about 2% to stabilizing effect on respiration during sleep, it has been held that where the general conditions of

a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. ***In re Aller*, 105 USPQ 233.**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772